

# United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

BETTINA POIRIER, MAJORITY STAFF DIRECTOR  
ZAK BAIG, REPUBLICAN STAFF DIRECTOR

June 25, 2014

The Honorable James J. Jones  
Assistant Administrator  
U.S. Environmental Protection Agency  
William Jefferson Clinton Building East  
1200 Pennsylvania Avenue NW (Mail Code: 7101M)  
Washington, DC 20460

Dear Assistant Administrator Jones:

As you are well aware, we keep a watchful eye on the U.S. Environmental Protection Agency's (EPA)'s scientific work. While great strides are needed in overall transparency, we appreciate the U.S. National Academy of Sciences' (NAS)'s recent guidance to EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) on how to conduct appropriate chemical risk assessments.<sup>1</sup> The NAS's guidance was the result of a long-standing history of concerns with EPA's poor management of the scientific process.<sup>2</sup> Unfortunately, it has come to our attention that despite recent NAS' guidance to OCSPP, as well as EPA's commitment to improve the conduct and reform OCSPP's risk assessment framework, OCSPP's staff is yet again "cherry-picking" scientific data in what appears to be a continued effort to further EPA's "windsock" approach for catering to the media at the expense of protecting human health and the environment by utilizing the best available science in its decision-making activities.

Our specific concerns involve OCSPP's workplan chemical risk assessment on trichloroethylene (TCE) (hereinafter the "TCE assessment").<sup>3</sup> The draft version of the TCE assessment did not identify risks based on Johnson *et al.* (2003);<sup>4</sup> however, the final assessment utilized the finding of cardiac malformation, as reported by Johnson *et al.* (2003), as the most sensitive basis from which to determine risk.<sup>5</sup> This is troubling not only because of the

<sup>1</sup> *Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic*, National Research Council of the National Academies, November, 7 2013. <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=18594>

<sup>2</sup> *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*, National Research Council of the National Academies, April 8, 2011. <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13142>; *Review of the Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as they Apply to Endocrine Disruptors*, National Research Council of the National Academies, May, 2 2014. [http://www.nap.edu/catalog.php?record\\_id=18608](http://www.nap.edu/catalog.php?record_id=18608)

<sup>3</sup> EPA (2012) *TSCA workplan chemical risk assessment for trichloroethylene: Degreaser and arts/crafts uses*, CASRN: 79-01-6, Ethene, 1,1,2-trichloro-, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, Washington, DC, 102 pp., available at: [http://www.epa.gov/oppt/existingchemicals/pubs/TSCA\\_Workplan\\_Chemical\\_Risk\\_Assessment\\_of\\_TCE.pdf](http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Workplan_Chemical_Risk_Assessment_of_TCE.pdf)

<sup>4</sup> Johnson *et al.* (2003) *Threshold of trichloroethylene contamination in maternal drinking water affecting fetal heart development in the rat*, ENVIRONMENTAL HEALTH PERSPECTIVES, Vol. 111, pp. 289-292.

<sup>5</sup> EPA (2014) *TSCA work plan chemical risk assessment for Trichloroethylene: Degreasing, Spot Cleaning and Arts and Crafts Uses*, CASRN: 79-01-6, Office of Chemical Safety and Pollution Prevention, U.S. Environmental

fundamentally flawed nature of this study,<sup>6</sup> but also because the external charge<sup>7</sup> for this assessment contained leading questions that favored its use. We were informed of this matter by EPA whistleblowers, who tracked the decisions with the TCE assessment, that Dr. Stan Barone, a Deputy Division Director within OPPT and the peer-review coordinator for workplan chemical risk assessments, worked on a previous TCE evaluation<sup>8</sup> and publications<sup>9</sup> that supported the Johnson *et al.* (2003) study.

Beyond concerns with OCSPP's decision to include this study, which was influenced by the peer reviewers' recommendations, it is our understanding that Dr. Barone was the primary individual who drafted the external charge to peer reviewers. This approach is tantamount to directing the outcome, based on the established views of one Agency scientist. To determine the extent of Dr. Barone's influence on this process, we are requesting copies of all documents related to the development of the TCE external charge, selection of peer reviewers, and the peer review, as well as a list of individuals who worked on the TCE external charge and/or peer review that we may question about this matter.

As you are clearly aware, we have closely followed the TCE assessment, as it is the first assessment to be completed under your new framework and is a chemical of significant public attention. The credibility of the TCE assessment will hinge upon the weight of the scientific evidence, which is supposed to be based upon the best available science. However, EPA's inclusion of the Johnson *et al.* (2003) study clearly deviates from any notions of working towards NAS's recommendations for higher scientific standards.

As you develop an appropriate response to this letter, we ask that you provide additional information related to a study Dr. Barone co-authored in 2001 titled "The effects of perinatal tebuconazole exposure on adult neurological, immunological, and reproductive function in rats."<sup>10</sup> Dr. Barone subsequently published a Letter to the Editor on this study in 2004, in which he withdrew "...all neuropathological conclusions in the paper..." due to questions that arose about the reported findings.<sup>11</sup> For some inexplicable reason that same year, Dr. Barone left a research-based position within the Office of Research and Development's (ORD)'s Neurotoxicology Division in Research Triangle Park, North Carolina, and took a non-research based position at ORD's National Center for Environmental Assessment in Washington, DC.

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Protection Agency, Washington, DC, available at:

[http://www.epa.gov/oppt/existingchemicals/pubs/TCE\\_OPPTWorkplanChemRA\\_FINAL\\_062414.pdf](http://www.epa.gov/oppt/existingchemicals/pubs/TCE_OPPTWorkplanChemRA_FINAL_062414.pdf)

<sup>6</sup> For discussion, see: Hardin *et al.* (2004) *Trichloroethylene and cardiac malformations*, ENVIRONMENTAL HEALTH PERSPECTIVES, Vol. 112, pp. A607-A608.

<sup>7</sup> EPA (2013) *OPPT charge to external peer reviewers for the review of the TSCA workplan chemical risk assessment of TCE*, 3 pp., available at: <http://www.scgcorp.com/tcl2013/pdfs/OPPT%20Charge.pdf>

<sup>8</sup> EPA (2011) *Toxicological review of trichloroethylene (CAS No. 79-01-6), In support of summary information on the Integrated Risk Information System (IRIS)*, U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-09/011F, 1,200 pp., at p. xxxvi, available at: <http://www.epa.gov/iris/toxreviews/0199tr/0199tr.pdf>

<sup>9</sup> See, e.g., Chiu *et al.* (2013) *Human health effects of trichloroethylene: Key scientific findings and scientific issues*, ENVIRONMENTAL HEALTH PERSPECTIVES, Vol. 121, pp. 303-311; See also: Brown Dzubow *et al.* (2010) *Early life stage exposure and potential developmental susceptibility to tetrachloroethylene*, BIRTH DEFECTS RESEARCH. PART B, DEVELOPMENTAL AND REPRODUCTIVE TOXICOLOGY, Vol. 89, pp. 50-65.

<sup>10</sup> Moser *et al.* (2001) *The effects of perinatal tebuconazole exposure on adult neurological, immunological, and reproductive function in rats*, TOXICOLOGICAL SCIENCES, Vol. 62, pp. 339-352.

<sup>11</sup> Barone and Moser (2004) *Letter to the Editor*, TOXICOLOGICAL SCIENCES, Vol. 77, p. 183.

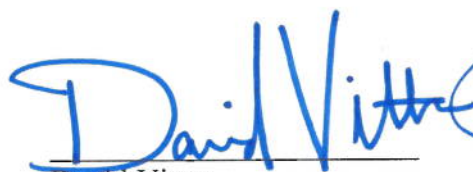


We are concerned that scientific misconduct related to his 2001 paper may exist, which would further impinge the credibility of Dr. Barone's handling of the TCE assessment, its external charge, and peer review. Therefore, we are requesting all communications related to the "[q]uestions [that] arose..."<sup>12</sup> regarding Dr. Barone's 2001 publication, the subsequent steps that ORD took to investigate the matter, ORD's findings, and a list of researchers familiar with the case for us to interview.

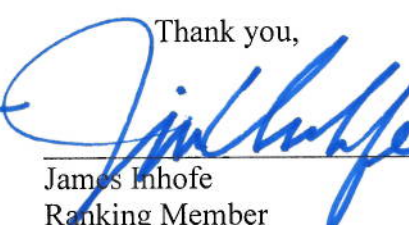
Beyond concerns with the Dr. Barone's scientific decisions, is an additional troubling matter involving the indication that Dr. Barone may have been promoted in October, 2013 without proper competition for his current position, as the Deputy Division Director of OCSPP's Risk Assessment Division (RAD). As you know, promoting an employee (*i.e.*, Dr. Stan Barone) or demoting an employee requires strict compliance with established rules of prohibited personnel practices.<sup>13</sup> Therefore, we are requesting all communications related to RAD's Deputy Director's position announcement, the selection process used, and a list of individuals within RAD, who were eligible to compete for this position, based on grade and time in service, as well as your knowledge of any employees that may have been demoted to facilitate Dr. Barone's promotion.

The issues highlighted in this letter are serious in nature in light of other recent revelations related to fraud, scientific misconduct, and mismanagement at the EPA. As there continue to be significant challenges with your Agency's ability to produce credible sound science in a transparent manner, we are certain you can appreciate the need for our offices to further investigate OCSPP, its scientific findings, and the processes used for promoting individuals to senior-level positions, who ultimately have decision-making authority on chemical risk assessments. Your cooperation in thoroughly and expeditiously responding to these issues no later than close of business (COB) on Wednesday, July 16, 2014, may help to alleviate the need to bring further details of these issues, as well as additional matters concerning your office, to public attention.

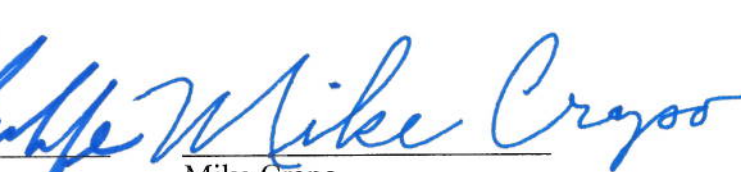
Thank you,



David Vitter  
Ranking Member  
Committee on Environment  
and Public Works



James Inhofe  
Ranking Member  
Subcommittee on Oversight



Mike Crapo  
Ranking Member  
Subcommittee on  
Superfund, Toxics and  
Environmental Health

Cc: Dr. Francesca Grifo, Science Integrity Official, U.S. Environmental Protection Agency

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<sup>12</sup> *Ibid.*

<sup>13</sup> Title 5 - Government Organization and Employees, Chapter 23 - Merit System Principles, Section 2302. Prohibited personnel practices, subpart b, available at: <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title5/pdf/USCODE-2010-title5-partIII-subpartA-chap23.pdf>